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RECORD OF ORAL HEARING

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BEFORE THE BOARD OF PATENT APPEALS

AND INTERFERENCES

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Ex Parte JOAN D. LEONARD, and ROBERT W. TULLY

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Appeal 2009-013864
Application 09/708,352
Technology Center 1600

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Oral Hearing Held: September 14, 2010

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Before ERIC B. GRIMES, FRANCISCO C. PRATS, and JEFFREY N. FREDMAN, *Administrative Patent Judges.*

APPEARANCES:

ON BEHALF OF THE APPELLANT:

JOSEPH A. COPPOLA, ESQUIRE
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The above-entitled matter came on for hearing on Tuesday, September 14, 2010, commencing at 9:00 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Victor Lindsay, a Notary Public.

THE USHER: Calendar Number 9, Appeal Number 2009-013864, Mr. Joseph Coppola. The podium, sir.

MR. COPPOLA: Thank you.

JUDGE GRIMES: Good morning.

MR. COPPOLA: Good morning, Your Honors. Are we waiting --

JUDGE GRIMES: You can take your time --

MR. COPPOLA: I'm sorry.

JUDGE GRIMES: You can take your time getting set up there, and when you get ready, you'll have 20 minutes to make your argument.

MR. COPPOLA: Thank you. Are we waiting for someone else?

JUDGE PRATS: No, we're not.

MR. COPPOLA: All right.

JUDGE PRATS: You're right, though. Sometimes the Examiners do show up.

MR. COPPOLA: Okay. So I don't need to reserve any time for rebuttal?

JUDGE PRATS: No.

MR. COPPOLA: Okay. Okay, I'm ready if everyone else is.

JUDGE GRIMES: Please, go ahead.

MR. COPPOLA: Good morning again. I'm Joe Coppola. I'm here for the Appellants, and we're going to be talking about a case in which the

appealed claims are all directed to vaccines against Mycoplasma bovis, which is a microorganism that infects cattle, causes diseases, and, in particular, it causes a disease called mastitis, and mastitis is a disease of the udders of cows. It causes lowered milk production and milk of poor quality and it's a big problem in the dairy industry. Excuse me.

There are two rejections. There's an anticipation rejection and an obviousness rejection, and we have argued in our Brief that the claims do not stand and fall together for both rejections, and I'd like to go over some of the limitations that we think distinguish the claims over the applied prior art.

The anticipation rejection is over a Ph.D. thesis by someone named *Boothby,* and we think that Claims 5, 6, and 54, which we argued separately in the Brief, distinguish over *Boothby* because they recite --

JUDGE FREDMAN: Should it not be in Claim 1, the things that they've agreed to?

MR. COPPOLA: Yes, but not for the reason that I'm going to go into here.

JUDGE FREDMAN: Oh.

MR. COPPOLA: The limitations that are in Claims 5, 6, and 54 are limitations directed to specific biotypes. Biotypes are defined in the specification as -- on page 5, as variants or strains of Mycoplasma bovis that can be distinguished by a particular characteristic, such as differences in DNA sequence. The claims that I just mentioned, 5, 6, and 54, recite Biotypes A, B, and C, which are biotypes that are isolated by the Inventors. There are specific strains or variants of Mycoplasma bovis. The *Boothby*

thesis discloses a strain of Mycoplasma bovis called California 201. There's nothing in the *Boothby* thesis that indicates that California 201 is either Strain A, B or C. The *Boothby* thesis was published in 1982. Our provisional was filed in 1999. The Inventors isolated Strains A, B, and C. And there is a lot of evidence in the record which says that there are many, many biotypes out there.

JUDGE FREDMAN: Well, one of the references indicated there were 37 different types.

MR. COPPOLA: Right. That's part of the evidence in the record. If you put all that together, it's our opinion that the prima facie case of obviousness has not made been made for Claims 5, 6, and 54.

JUDGE PRATS: If I could refer you to page 13 of the specification, it lists 1, 2, 3, 4, 5, 6, 7, about 10 strains. Are any of those California 201?

MR. COPPOLA: I don't believe so, but give me a moment, please, to find the spec.

JUDGE PRATS: If you know.

MR. COPPOLA: Where is it? I'm very sorry. I thought I had it here. I can't believe I don't.

JUDGE PRATS: That' s okay. I'll just -- I'll rephrase it. Do you know if California 201 is any of the -- is one of the strains that was tested by the Inventors and disclosed in the specification?

MR. COPPOLA: We don't know that for sure, but it seems very unlikely given how many strains are out there and the fact that the Inventors isolated their own strains.

Okay, I'd like to move on to the next limitation, which is in Claims 29, 30, and 40 to 44. It's in other claims, but I should have said that the anticipation rejection has only been applied to some of the appealed claims. These claims, 29, 30, and 40 through 44, recite that the claimed vaccine needs to be protective against mastitis. Now, the Examiner's Answer took the position that that's an intended use. It's our position that rather than an intended use, it's a functional limitation which distinguishes over *Boothby's* vaccine.

JUDGE FREDMAN: But the Examiner has a vaccine which is -- would be due to the vaccine which is against the bovis. I don't think it tells us whether it's effective against mastitis --

MR. COPPOLA: That's right.

JUDGE FREDMAN: -- but why would that not be apparent?

MR. COPPOLA: Right. The Examiner is using the inherency to find this limitation.

JUDGE FREDMAN: Then why would that not be the case?

MR. COPPOLA: Because there is evidence in the record that indicates that even though *Boothby* was published in '82, through the 90s and 2001, people skilled in the art were treating -- were operating under the assumption that a vaccine that's effective against -- that protects against mastitis didn't -- wasn't available.

JUDGE FREDMAN: Well, but that doesn't really tell us anything because for all we know *Boothby* had a patent himself and wasn't licensing to anyone. I mean, there's no reason to assume specifically if *Boothby* published something there was a -- it was necessarily an available vaccine.

What if people, for cost reasons or other reasons, chose to use it even if it was available?

MR. COPPOLA: That is possible.

JUDGE FREDMAN: I mean, I don't think that just negative evidence that the dog didn't bark at night proves your point.

MR. COPPOLA: I understand that --

JUDGE FREDMAN: Do you have any positive evidence --

MR. COPPOLA: None of these references make a clear statement that no vaccine was available --

JUDGE FREDMAN: And the burden --

MR. COPPOLA: -- but it seems to us it's a reasonable inference.

JUDGE FREDMAN: Right, but the burden under *In Re Best* (ph.), is shifted to you, I think reasonably, by this Examiner. He has shifted the burdens and I have an inherent reference. It's vaccine. It raises, you know, immune response. It apparently seems to work. Why it wouldn't protect, I think, then becomes your burden.

MR. COPPOLA: Well, it's -- when you said it appears to work, that's against respiratory diseases which are very different from mastitis, which is a disease of the udder. *Boothby* was --

JUDGE FREDMAN: I understand, but he has a working vaccine and I think that the burden then shifts. We don't have a lab, or the Examiner certainly doesn't have a lab.

MR. COPPOLA: I'm sorry, the Examiner doesn't?

JUDGE FREDMAN: Doesn't have a laboratory, right?

MR. COPPOLA: Oh, yes. Right. I understand.

JUDGE FREDMAN: That's the whole reasoning under *Best,* that the Patent Office can't test it themselves.

MR. COPPOLA: I understand.

JUDGE GRIMES: Do you -- is there any evidence in the record of other references where they've tried particular vaccines against this bacterium and it didn't work to prevent mastitis?

MR. COPPOLA: There is, and that's part of the evidence in the record. There's another paper by -- a scientific paper by *Boothby*. We assume it's the same *Boothby.* It seems to be the same investigator, and that's *Boothby II* in the evidence of record.

JUDGE FREDMAN: Okay. Can we see that?

JUDGE GRIMES: And what does that show?

MR. COPPOLA: It shows that a vaccine, which seems to be very similar to the one in *Boothby's* Ph.D. thesis, couldn't do much against mastitis. In that paper, *Boothby* and his coauthors treated cows with killed Mycoplasma bovis and then challenged them with infectious Mycoplasma bovis, and what they found was that, on the whole, it's our opinion that giving the killed -- if I call it a vaccine -- giving the killed microorganisms led to worse outcomes. There's a figure in that paper on Figure 2 which we've reproduced in our Reply that says -- or it shows that the worst outcome in terms of milk production came from the cows that were vaccinated.

JUDGE PRATS: All right, doesn't the Examiner take issue with this? The Examiner -- you all are butting heads on this issue. You're saying, well, milk production went down, but the Examiner says -- as disclosed in the

abstract and elsewhere in his article, it says that, in fact, by the end of the study no m-bovis could be recovered from challenged quarters on vaccinating cows and that milk appeared mostly normal. So the Examiner is saying if you can't find the bug on the udders, then that shows that this actually was effective.

MR. COPPOLA: Okay, two things about that. First of all, it says by the end of the study, and that, to our mind, is an indication that eventually the cows recovered, which even if they get sick they do recover from mastitis eventually. I -- we think that's what happened.

The second thing is that there's a lot of -- there are a lot of things measured in this paper. Some of them seem to be a little better for the control cows but, in our opinion, most of them seem to indicate that the vaccinated cows did worse. And I'd like to read something -- oh, excuse me. I have a problem in that I need these for distance but not for close-up viewing, so I need to --

JUDGE PRATS: I'm just the opposite. We're all getting older.

MR. COPPOLA: I guess maybe you need to change too back and forth.

Anyway, on page 202, right column, last paragraph of this *Boothby II*, all experimentally challenged quarters developed CMT reactivity. CMT reactivity is a test to show that there is Mycoplasma bovis present. So all experimentally challenged quarters means that every udder that was given live m-bovis became infected, so the vaccine didn't protect. Then it goes on to say all challenged quarters on vaccinated cows remained CMT positive for the duration of this study, while some challenged quarters on control

cows became CMT negative. So, there, you have a disclosure which indicates that the control cows, the cows that didn't get the killed m-bovis, did better than the vaccinated cows. And that's what I mean by most of the evidence in this paper, to our reading at least, indicates that the vaccine didn't work. And again, this was by the author of *Boothby I*.

JUDGE FREDMAN: Do we know that it's the same vaccine or --

MR. COPPOLA: We don't, no. It appears to have -- there's very sketchy --

JUDGE FREDMAN: Is it the very same organism?

MR. COPPOLA: I think it was California 201.

JUDGE FREDMAN: It says here, it says California 201. Okay.

MR. COPPOLA: Yes. And there are very few details about how it was prepared and how it was grown and so on, but given the little detail that's there, it seems very similar to what was in the *Boothby* thesis.

JUDGE FREDMAN: Okay.

MR. COPPOLA: If there are no more questions about this issue, this limitation, I'd like to move on.

Okay, Claims 52 and 55 recite the *Markush* group of certain adjuvants, and the Examiner's Answer -- we're back to anticipation and *Boothby* -- the Examiner said that *Boothby I*, the *Boothby* thesis, discloses aluminum hydroxide and for that reason meets these claims, meets that *Markush* group. But if you look at the *Markush* group, what it actually says is aluminum hydroxide oil emulsion, which is not the same as just aluminum hydroxide. And if you look at the *Boothby* thesis, it discloses that the

aluminum hydroxide was present in an aqueous solution. So we're asking that you withdraw this rejection of Claims 52 and 55 for that reason.

JUDGE PRATS: I'm sorry, I missed this -- that argument, where it is in your Brief.

MR. COPPOLA: Oh, I believe it's there. It would probably be towards the end of the discussion on anticipation. Here's the missing specification. Excuse me. Do you know how much time I've used?

JUDGE GRIMES: We'll let you go beyond your 20 minutes since we're asking questions.

MR. COPPOLA: Oh, well, thank you.

JUDGE GRIMES: And can you lift things up --

MR. COPPOLA: Okay, page 18 --

JUDGE FREDMAN: Of the Brief?

MR. COPPOLA: Yeah. We pointed to a list of adjuvants -- in the Brief, we pointed to a list of adjuvants and said it doesn't disclose, and none of these adjuvants are the adjuvants in the *Markush* group. Then in the Examiner's Answer, the Examiner said, hey, what about aluminum hydroxide? And then in our Reply, we said it's not -- I think we addressed it. Maybe we didn't. But at any rate, it is in the Brief. The claims are argued separately on page 18. Anything else on the issue of adjuvants? Okay, if there are no more questions about anticipation, I'd like to move on to obviousness.

JUDGE FREDMAN: Well, you didn't really address Claim 1, though. Do you have any arguments from Claim 1 or --

MR. COPPOLA: No, I wasn't prepared to talk about that. I had to decide what I could fit into the 20 minutes and --

JUDGE FREDMAN: Okay. Thank you.

MR. COPPOLA: I don't want to say I'm withdrawing it --

JUDGE FREDMAN: That's fine.

MR. COPPOLA: -- but I don't want to address it.

JUDGE FREDMAN: Sure. I understand.

MR. COPPOLA: Thanks. Okay, for obviousness, we have Claims 8 through 12, 31 through 39, and 46 through 51 that we argued separately, and as a subset of those claims, Claims 34 through 39 and 46 through 51, which we also argued separately, both of those subsets of claims, or both of those groups of claims recite at least two biotypes. For the second group of claims, 34 to 39 and 46 to 51, the two biotypes must be distinguished by DNA or RNA sequence, genetically different --

JUDGE FREDMAN: Aren't any two biotypes going to necessary be distinguished by DNA sequence? That is, if they're antigenically different in any way, at least the antigen itself will have to have at least a DNA difference or you won't -- at looks to me that way. So isn't that kind of an almost necessary property? It's almost impossible not to have that active?

MR. COPPOLA: Well, you could have DNA sequence differences that don't show up antigenically. You know, they could be for rivasolarene (ph.) --

JUDGE FREDMAN: Right.

MR. COPPOLA: -- or something that generally doesn't raise an immune response.

JUDGE FREDMAN: But the reference is -- I think the reference teaches these in two different ones, right? I mean, so the question is it's hard for them to have a reference teaching two different antigens that are not significantly different. Right here, I see that you could have, you know, even ones that are antigenically the same but different in the DNA, but it'd be hard to be antigenically different and not be different in the DNA.

MR. COPPOLA: Okay, I see what you're saying. I -- that sounds right on first hearing to me, yes.

JUDGE FREDMAN: Okay.

MR. COPPOLA: The key reference for this group of claims of *Poumarat*, which is a publication that studied the isolation of 37 different m-bovises and was able to group those m-bovises into what are called 13 genomic groups. *Poumarat* looked at the DNA by restriction enzyme analysis and found certain patterns and some of the isolates have the same pattering equivalent in one group. Other isolates had a different pattern if you'd put them in another genomic group. After doing that, *Poumarat* looked at the antigenicity, the antigenic variability, as he called it, of the different genomic groups. Excuse me for a moment. And this may be my most important point here. *Poumarat* found when he looked at the antigenic variability of the genomic groups, when he looked at strains within one genomic group, they had a lot of antigenic variability and the antigenic variability within groups, *Poumarat* said, was equal to the antigenic variability when you compare groups, and what that says to -- we have a quote from page 318 in our Brief in which *Poumarat* makes statements to that effect. What that says to us is that one of ordinary skill in the art

looking at those statements would say, well, I'm going to make a vaccine. I'd like antigenic variability in my vaccine because that will give me a broader scope of protection but, according to *Poumarat*, I'd get all of that antigenic variability by using one genomic group. It -- there's cost time expense involved in using more than one genomic group. You have to -- if you're just going from one to two, you double all of those things, the cost, the time, and the expense, that are associated with preparing the group, the biotype for the vaccine. So looking at all of that, one of ordinary skill in the art would say why would I use two? I'm better off using one. It's simply cheaper. It'd give me the same effect. I'd be deterred from using two.

JUDGE FREDMAN: Doesn't the very last, at page 319 of *Poumarat*, the very last paragraph, pretty much say that two highly variable antigenic systems have been identified so far for m-bovis, but their individual function was not known? So given that there's two antigenic systems, wouldn't you pick two?

MR. COPPOLA: I don't think so. That's a little different from what I was talking about. That paragraph refers to the work with monoclonal antibodies which, I think you know, focus on one protein.

JUDGE FREDMAN: Right.

MR. COPPOLA: What he found was that for some monoclonal antibodies a membrane antigen appeared to be in two different states.

JUDGE FREDMAN: Okay.

MR. COPPOLA: But there's nothing in *Poumarat* which indicates -- you probably would want to hit both of those states in your vaccine, but there's nothing in *Poumarat* that indicates you need to have two genomic

groups to do that because the variability is the same within, even for this presumably, although *Poumarat* doesn't address it specifically. Presumably, for this type of variability, it's the same within the group as it is across the groups.

JUDGE GRIMES: So as I understand it, your argument is that *Poumarat's* genomic groups correspond to the biotypes that are recited in the claims?

MR. COPPOLA: Yes, especially Claims 34 to 39 and 46 to 51 because --

JUDGE GRIMES: But your specification has a very broad definition of biotypes.

MR. COPPOLA: It does, yes.

JUDGE GRIMES: It just requires some kind of DNA difference?

MR. COPPOLA: Right.

JUDGE GRIMES: And as Judge Fredman was saying, if you've got an antigenic difference between two strains, even if they're within the same genomic group, it would seem likely, if not certain, that there's a DNA difference behind that antigenic difference?

MR. COPPOLA: That's right.

JUDGE GRIMES: So why do we have to go to different genomic groups to get different biotypes?

MR. COPPOLA: Well, you don't -- you do for Claims 34 to 39 and 46 to 51 because biotypes in those claims is restricted. Along the same lines as *Poumarat* --

JUDGE GRIMES: Counsel, I'm sorry. Explain that. I'm looking at Claim 34. It says that at least two inactivated or attenuated Mycoplasma bovis biotypes are genetically different as determined by an analysis of DNA or RNA from the biotypes. So why doesn't that just require some kind of DNA sequence difference between the two types of m-bovis?

MR. COPPOLA: I think it does.

JUDGE GRIMES: Okay. And why -- in *Poumarat*, within a single genomic group, if you have antigenically different microorganisms in there, why would you expect that they would not have a DNA difference?

MR. COPPOLA: I think I see your point. I guess they would. I think I see your point. I wish I had more time to think about it. This is the first time it's come up during prosecution. Could we maybe remand for that if you find that's a reason to sustain or to make a new rejection, perhaps, a new argument?

JUDGE GRIMES: I think we'll have to see how our thinking comes out after this argument.

MR. COPPOLA: Just please consider that. It is the first time we've heard that. It hasn't come up. Okay, that's probably all I have to say about that issue.

The next issue, the next set of limitations is, again, protection against mastitis, and that's Claims 29, 30, and 40 to 45. And this an obviousness rejection and it looks to us as though *Boothby II*, that is, the *Canadian Journal of Veterinary Medicine* article, teaches away from that limitation. It shows failure of others, and, again, our reading of that publication is that on

the whole it pretty clearly indicates that the vaccinated cows did worse. That would deter someone from trying to repeat it.

JUDGE GRIMES: Okay, I think we've covered that particular issue.

MR. COPPOLA: Right. The last thing I have to talk about is Claim 56, which is an -- it requires an attenuated Mycoplasma bovis, and there is nothing -- the only one of the three references used to support the obviousness rejection that has anything to do with attenuated m-bovis is *Thorns* (ph.) and that at the very end has a statement which indicates that at least the authors of *Thorns* felt that what was disclosed in *Thorns* were not vaccines, that they could perhaps lead to production of vaccines, that's, you know, with more work being done, so --

JUDGE FREDMAN: With the attenuated variance, I mean, that's -- an ordinary artisan knows that one can attenuate a virus for vaccines. You know, it's a pretty standard procedure since the original rabies vaccine. All right, so --

MR. COPPOLA: Right. Well, yes. For the most part, that's true, yes.

JUDGE FREDMAN: Okay.

MR. COPPOLA: I have nothing else unless you have further questions.

JUDGE FREDMAN: Okay.

JUDGE PRATS: I have nothing.

MR. COPPOLA: Okay.

JUDGE GRIMES: Thank you for coming in.

MR. COPPOLA: Thank you. Thank you for the opportunity.

Whereupon, the proceedings, at 9:25 a.m., were concluded.